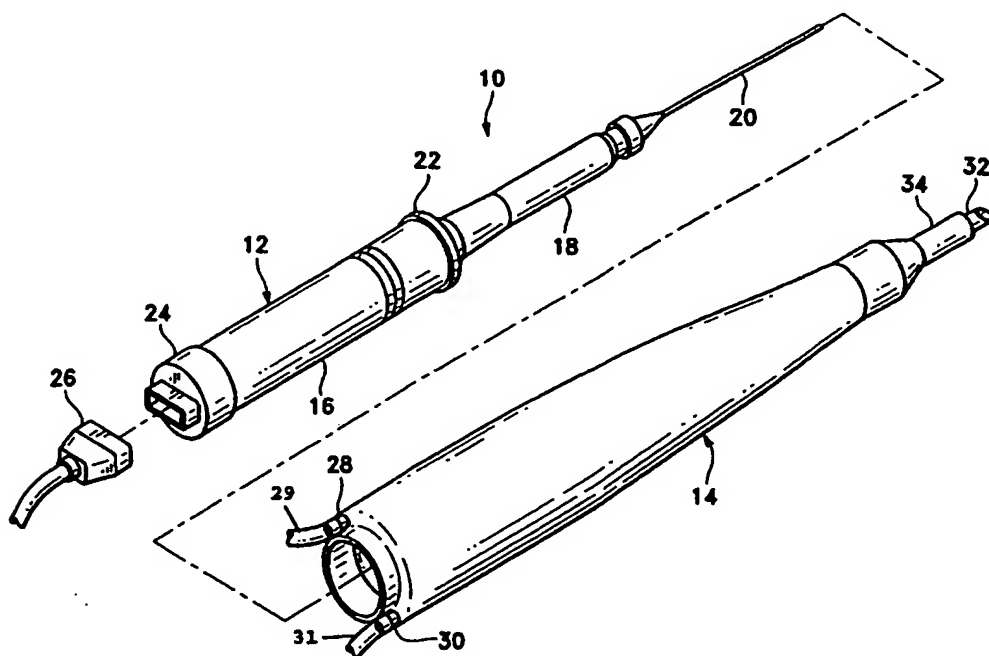




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶: A61F 9/007, A61B 17/32 // 19/00	A1	(11) International Publication Number: WO 99/15120 (43) International Publication Date: 1 April 1999 (01.04.99)
(21) International Application Number: PCT/US98/14767 (22) International Filing Date: 16 July 1998 (16.07.98) (30) Priority Data: 08/935,797 23 September 1997 (23.09.97) US (71) Applicant: ALCON LABORATORIES, INC. [US/US]; 6201 South Freeway, Fort Worth, TX 76134-2099 (US). (72) Inventor: CAPETAN, Thomas, G.; 3817 Mockingbird Lane, Fort Worth, TX 76109 (US). (74) Agents: SCHIRA, Jeffrey, S. et al.; Alcon Laboratories, Inc., R & D Legal Dept., Q-148, 6201 South Freeway, Fort Worth, TX 76134-2099 (US).		(81) Designated States: AU, BR, CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>

(54) Title: SURGICAL HANDPIECE**(57) Abstract**

A surgical handpiece having a central operative core which is removably received in an outer shell. The operative core and outer shell is easier to manufacture and assemble, thereby decreasing cost and increasing reliability.

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SURGICAL HANDPIECE

This invention relates to surgical handpieces and more particularly to an ophthalmic phacoemulsification handpiece.

Background of the Invention

A typical ultrasonic surgical device suitable for ophthalmic procedures consists of an ultrasonically driven handpiece, an attached hollow cutting tip, an irrigating sleeve and an electronic control console. The handpiece assembly is attached to the control console by an electric cable and flexible tubings. Through the electric cable, the console varies the power level transmitted by the handpiece to the attached cutting tip and the flexible tubings supply irrigation fluid to and draw aspiration fluid from the eye through the handpiece assembly.

The operative part of the handpiece is a centrally located, hollow resonating bar or horn directly attached to a set of piezoelectric crystals. The crystals supply the required ultrasonic vibration needed to drive both the horn and the attached cutting tip during phacoemulsification and are controlled by the console. The crystal/horn assembly is suspended within the hollow body or shell of the handpiece at its nodal points by relatively inflexible mountings. The handpiece body terminates in a reduced diameter portion or nosecone at the body's distal end. The nosecone is externally threaded to accept the irrigation sleeve. Likewise, the horn bore is internally threaded at its distal end to receive the external threads of the cutting tip. The irrigation sleeve also has an internally threaded bore that is screwed onto the external threads of the nosecone. The cutting tip is adjusted so that the tip projects only a predetermined amount past the open end of the irrigating sleeve. Ultrasonic handpieces and cutting tips are more fully described in U.S. Pat. Nos. 3,589,363; 4,223,676; 4,246,902; 4,493,694; 4,515,583; 4,589,415; 4,609,368; 4,869,715; 4,922,902 and 5,178,605 the entire contents of which are incorporated herein by reference.

When used to perform phacoemulsification, the ends of the cutting tip and irrigating sleeve are inserted into a small incision of predetermined width in the cornea, sclera, or other location in the eye tissue in order to gain access to the anterior chamber of the eye. The cutting tip is ultrasonically vibrated along its longitudinal axis within the

irrigating sleeve by the crystal-driven ultrasonic horn, thereby emulsifying upon contact the selected tissue in situ. The hollow bore of the cutting tip communicates with the bore in the horn and the piezoelectric crystals that in turn communicates with the aspiration line from the handpiece to the console. A reduced pressure or vacuum source in the console
5 draws or aspirates the emulsified tissue from the eye through the open end of the cutting tip, the bore of the cutting tip, the horn bore, and the aspiration line and into a collection device. The aspiration of emulsified tissue is aided by a saline flushing solution or irrigant that is injected into the surgical site through the small annular gap between the inside surface of the irrigating sleeve and the outside surface of the cutting tip. This small
10 annular gap separates the vibrating, hot tip from eye tissue and the flow of fluid within the gap cools the tip. In some cases, the gap and the fluid flow are insufficient to prevent the burning of tissue.

Prior to the present invention, phacoemulsification handpieces were relatively expensive due to the cost of the materials and the precise machining required in
15 manufacturing the handpieces. As a result, phacoemulsification handpiece are not disposed of at the end of surgery, but are reused a number of times. Handpieces that are reused must be sterilized, usually by steam autoclaving. Steam autoclaving is extremely injurious to the seals, piezoelectric crystals and other electrical components of the handpiece. As a result, prior art phacoemulsification handpieces can be unreliable and
20 must be rebuilt frequently. Additionally, prior art handpieces require numerous connections to a surgical console, making the handpieces more difficult and time consuming to set up.

Accordingly, a need continues to exist for a simple, reliable and safer surgical handpiece.

Brief Summary of the Invention

The present invention improves upon prior art handpieces by providing a handpiece having a central core which is removably received in an outer shell. The central core may
30 be an ultrasonic element, a laser element or any other desired operative core and the core and/or the outer shell may be intended as a single use disposable or reusable element. A separate core and outer shell is easier to manufacture and the core does not have to be

steam autoclaved. In addition, all the required connections for the handpiece can be preassembled on the handpiece and for easy connection to the surgical console, thereby reducing set up time.

Accordingly one objective of the present invention is to provide an inexpensive surgical handpiece.

Another objective of the present invention is to provide a surgical handpiece having increased reliability.

Still another objective of the present invention is to provide a phacoemulsification handpiece having a solid resonating core and tip.

Other objects, features and advantages of the present invention will become apparent with reference to the drawings, and the following description of the drawings and claims.

Brief Description of the Drawings

FIG. 1 is an expanded prospective view of the first embodiment of the surgical handpiece of the present invention.

FIG. 2 is a cross-sectional view of the first embodiment of the surgical handpiece of the present invention.

FIG. 3 is a cross-sectional view of the second embodiment of the surgical handpiece of the present invention.

FIG. 4 is an expanded prospective view of the second embodiment of the surgical handpiece of the present invention.

Detailed Description of the Invention

As best seen in FIG. 1, handpiece 10 of the present invention preferably may be a phacoemulsification handpiece which will generally includes resonating core 12 and outer shell 14. Core 12 generally includes piezoelectric crystal portion 16, horn 18 and solid tip 20. Horn 18 and tip 20 preferably are machined as a single piece from any suitable material, for example, titanium, but the tip can be removable using a screw connector. Crystals 16 are attached to horn 18 at one end 22 by any suitable means, for example,

epoxy glue and contain electrical connector and seal 24 at the opposite end that allows handpiece 10 to be connected to a suitable power and control source (not shown) through cable 26. Crystals 16 are caused to vibrate in a manner well-known in the art.

Handpiece 10 may also be used as a laser handpiece, an irrigation/aspiration
5 handpiece, a liquefaction handpiece or any other desired handpiece by appropriate substitution of core 12.

Shell 14 contains aspiration port 28, irrigation port 30, integral aspiration sleeve 32
and integral irrigation sleeve 34. As best seen in FIG. 2, aspiration port 28 communicates
with aspiration sleeve 32 through internal aspiration line 36, and irrigation port 30
10 communicates with irrigation sleeve 34 through internal irrigation line 38. The use of
dual sleeves 32 and 34 provides further isolation of tip 20 from tissue. Shell 14 may be
made of any suitable material such as stainless steel, titanium or plastic. Suitable external
tubings 29 and 31 can be preassembled to aspiration port 28 and irrigation port 30 and
made to conveniently connect to the surgical console (not shown), for example, by
15 preconnecting tubings 29 and 31 to the surgical cassette (not shown) that may be used
with the console.

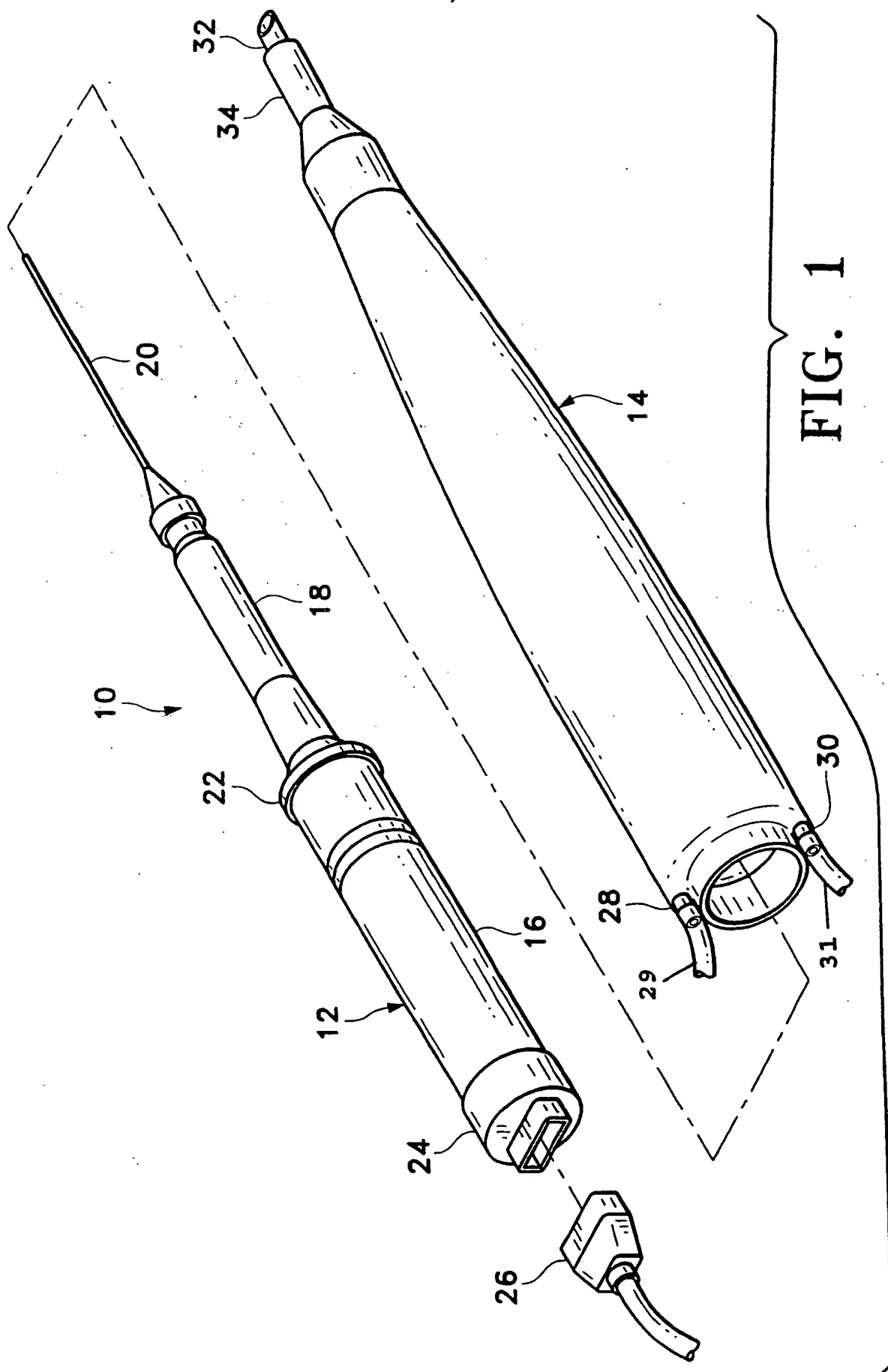
As best seen in FIGS. 2 and 3, when core 12 is inserted into shell 14, tip 20 is
coaxially sealed fluid tight within aspiration sleeve 32 by seal 40. Core 12 may be sealed
within shell 14 by a friction connector/seal 24, as shown in FIGS. 1 and 2, or screw
20 connector/seal 124, as shown in FIGS. 3 and 4.

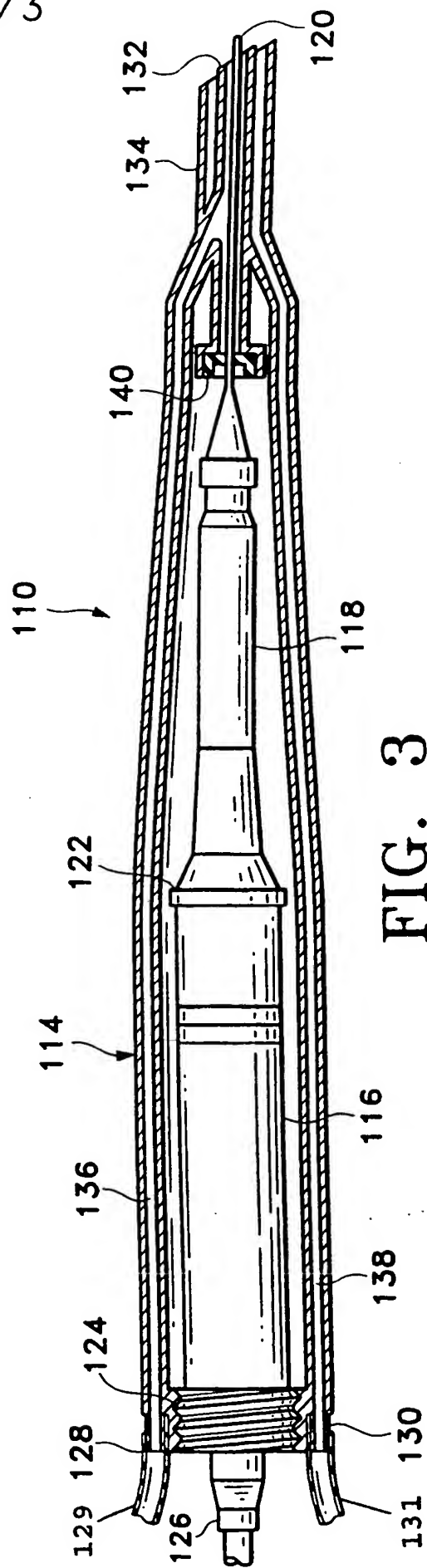
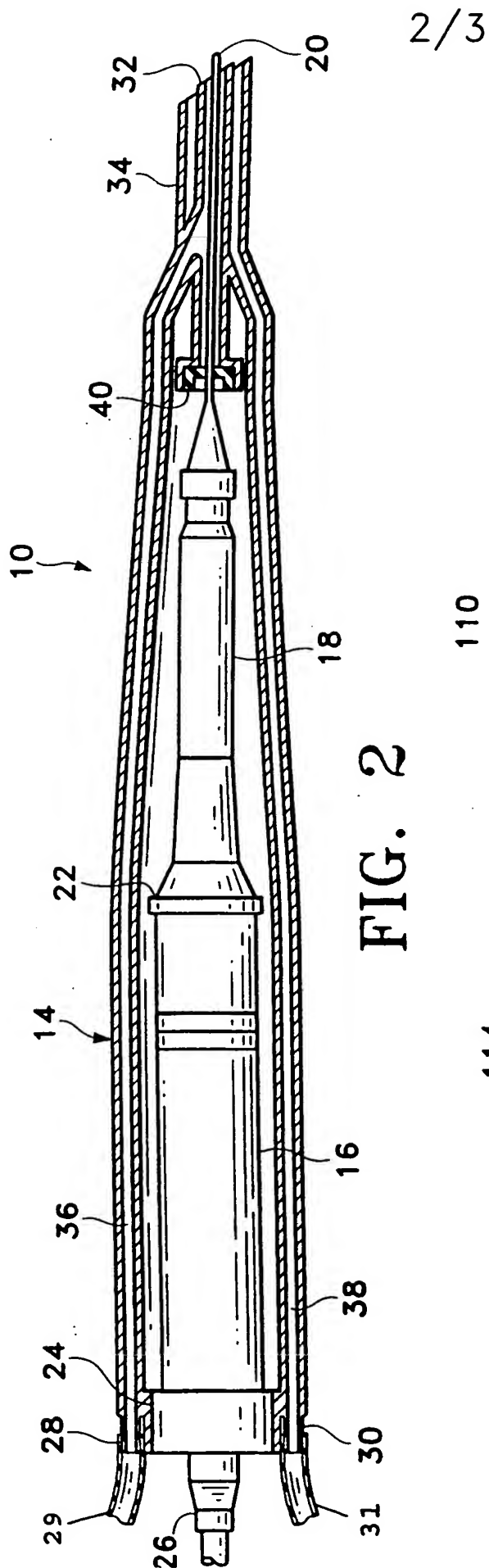
While certain embodiments of the present invention have been described above,
these descriptions are given for purposes of illustration and explanation. Variations,
changes, modifications and departures from the systems and methods disclosed above may
be adopted without departure from the scope or spirit of the present invention.

I claim:

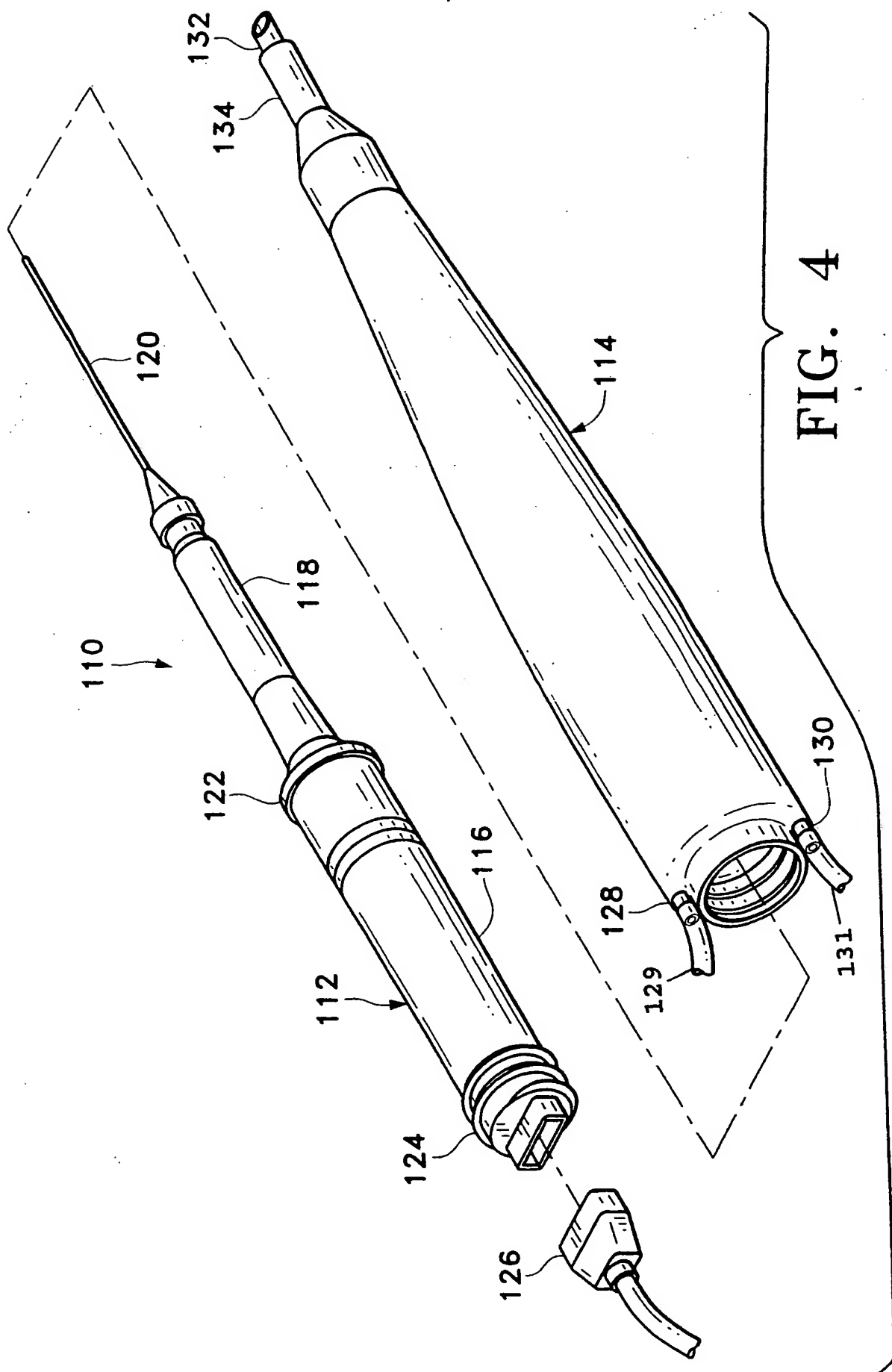
- 1 1. A surgical handpiece, comprising:
 - 2 a) a core having a piezoelectric crystal portion and a horn portion, the horn
 - 3 portion having an integral solid cutting tip and attached to the crystal portion;
 - 4 b) a hollow outer shell having internal aspiration and irrigation lines that
 - 5 communicate with integral aspiration and irrigation sleeves, respectively, the shell
 - 6 adapted to receive the core;
 - 7 c) a seal for sealing the solid cutting tip within the irrigation sleeve; and
 - 8 d) a connector for sealing the core within the shell.
- 1 2. The handpiece of claim 1 wherein the connector is a friction seal.
- 1 3. The handpiece of claim 1 wherein the connector is a screw seal.
- 1 4. The handpiece of claim 1 wherein external tubings are preassembled to
2 ports on the shell.
- 1 5. A surgical handpiece, comprising:
 - 2 a) an operative core;
 - 3 b) a hollow outer shell having internal aspiration and irrigation lines that
 - 4 communicate with integral aspiration and irrigation sleeves, respectively, the shell
 - 5 adapted to receive the core; and
 - 6 c) a connector for sealing the core within the shell.
- 1 6. The handpiece of claim 5 wherein the connector is a friction seal.
- 1 7. The handpiece of claim 5 wherein the connector is a screw seal.
- 1 8. The handpiece of claim 5 wherein external tubings are preassembled to
2 ports on the shell.

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 98/14767

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 9/007, A61B 17/32 // A 61 B 19/00

According to International Patent Classification (IPC) or to both national classification and IPC

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Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B, A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 3805787 A (A. BANKO), 23 April 1974 (23.04.74), column 5, line 8 - line 35, figure 4 --	1-8
Y	US 3994297 A (J.D. KOPF), 30 November 1976 (30.11.76), column 2, line 5 - line 14, figures 1-2 --	1-8
A	US 4316465 A (R.S. DOTSON, JR.), 23 February 1982 (23.02.82), figures 1-3 --	1-8
A	US 5344395 A (M.J. WHALEN ET AL.), 6 Sept 1994 (06.09.94), figures 1-4 --	1-8

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

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Date of the actual completion of the international search

18 December 1998

Date of mailing of the international search report

12.01.99

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INTERNATIONAL SEARCH REPORT

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 8903202 A1 (SCHNEIDER, RICHARD, T.), 20 April 1989 (20.04.89), figure 2 --	1-8
A	WO 9218075 A1 (ALLERGAN, INC.), 29 October 1992 (29.10.92), figures 8-9 -- -----	1-8

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Information on patent family members

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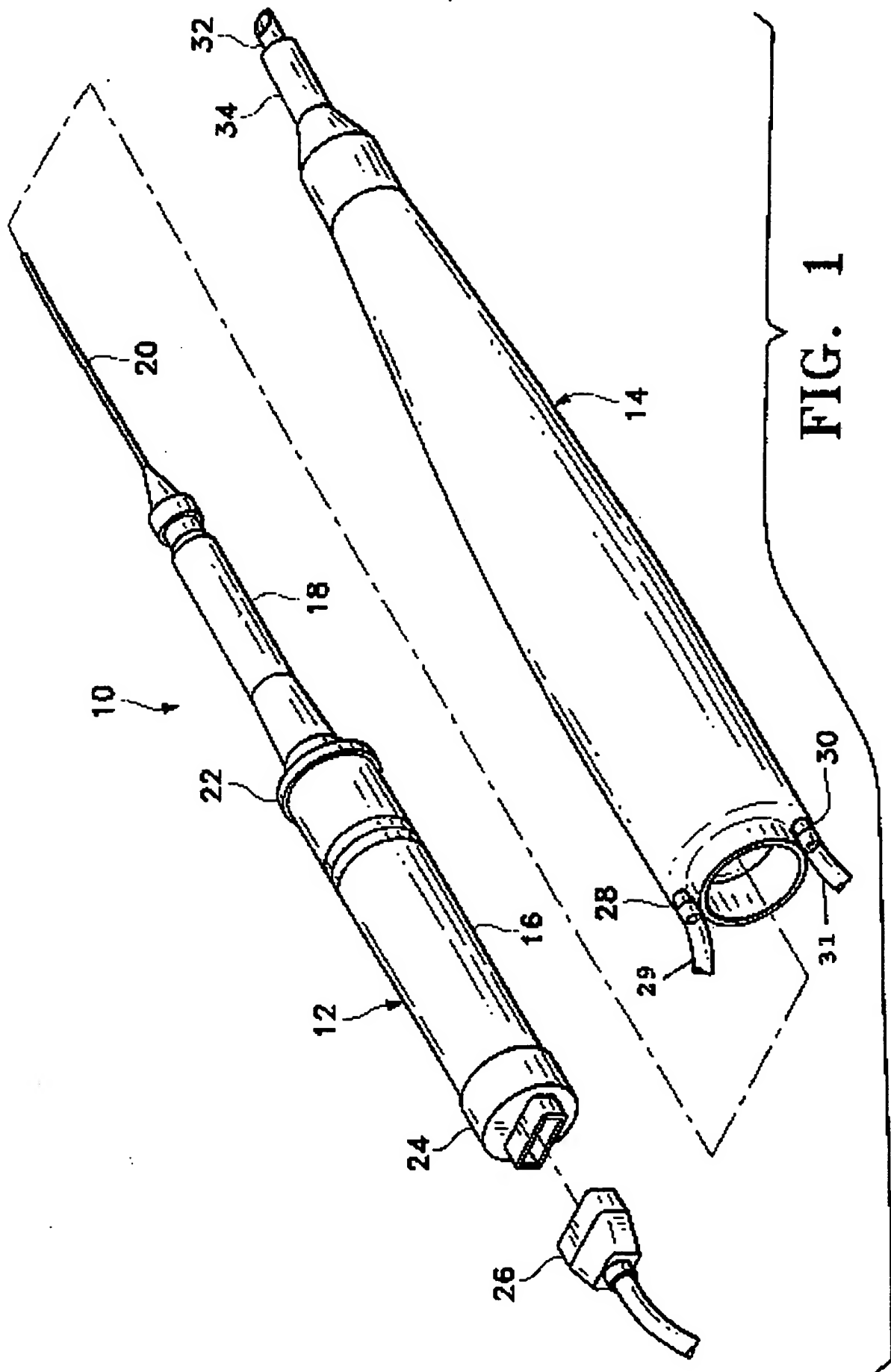
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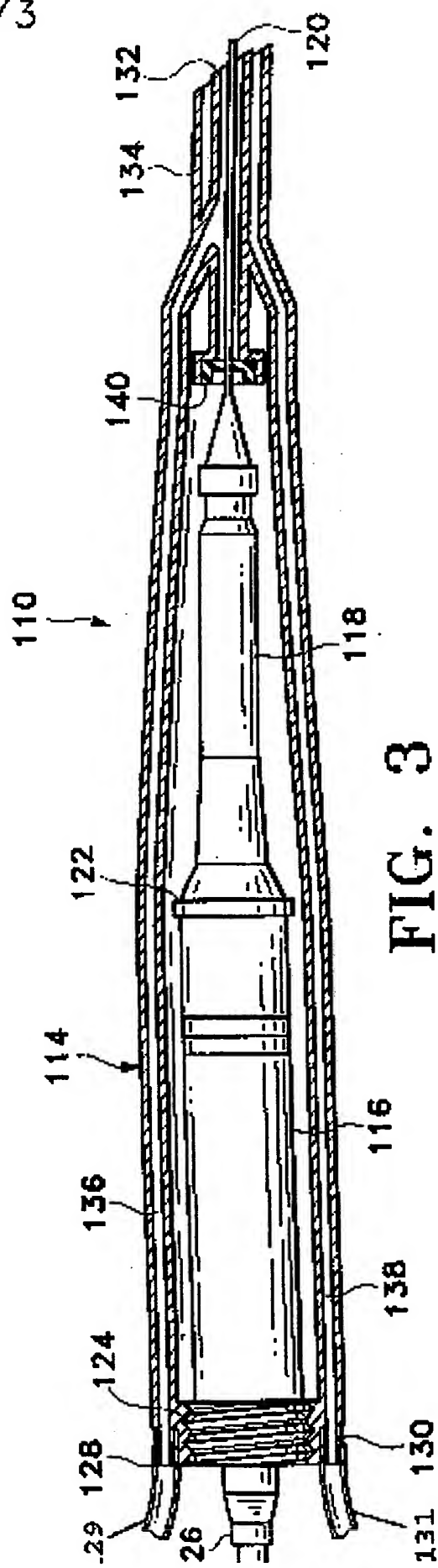
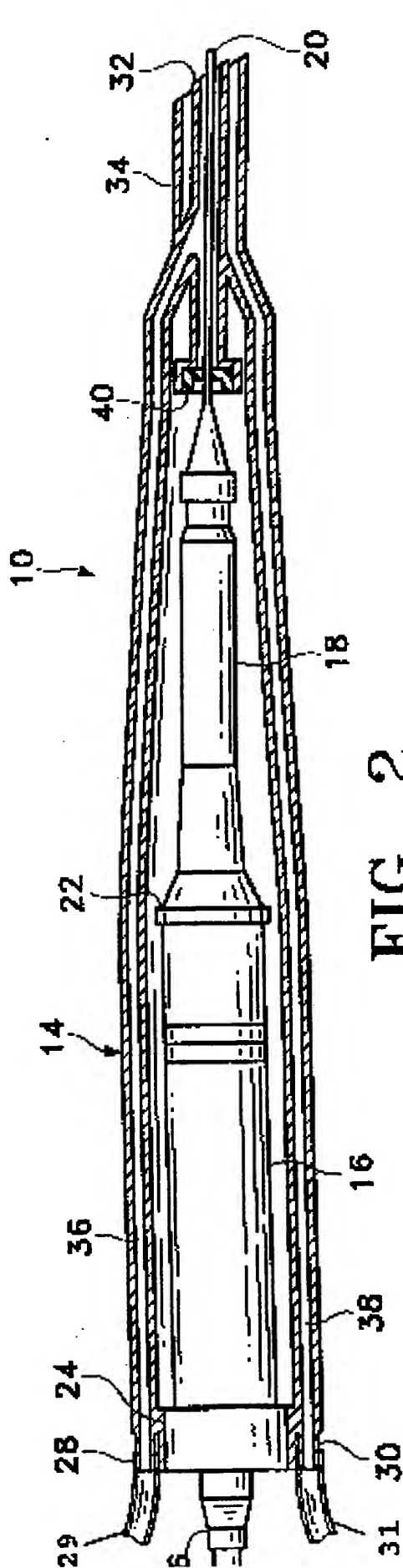
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Patent document cited in search report			Publication date	Patent family member(s)	Publication date
US	3805787	A	23/04/74	NONE	
US	3994297	A	30/11/76	NONE	
US	4316465	A	23/02/82	US 4274411 A	23/06/81
US	5344395	A	06/09/94	US 5085662 A	04/02/92
				US 5423838 A	13/06/95
				CA 2083525 A	25/07/93
				EP 0554616 A	11/08/93
				JP 5261114 A	12/10/93
WO	8903202	A1	20/04/89	NONE	
WO	9218075	A1	29/10/92	AT 153525 T	15/06/97
				DE 69220056 D,T	30/10/97
				EP 0585322 A,B	09/03/94
				JP 6507094 T	11/08/94
				US 5242449 A	07/09/93
				US 5364405 A	15/11/94
				AU 3697993 A	21/10/93
				CA 2092746 A	17/10/93

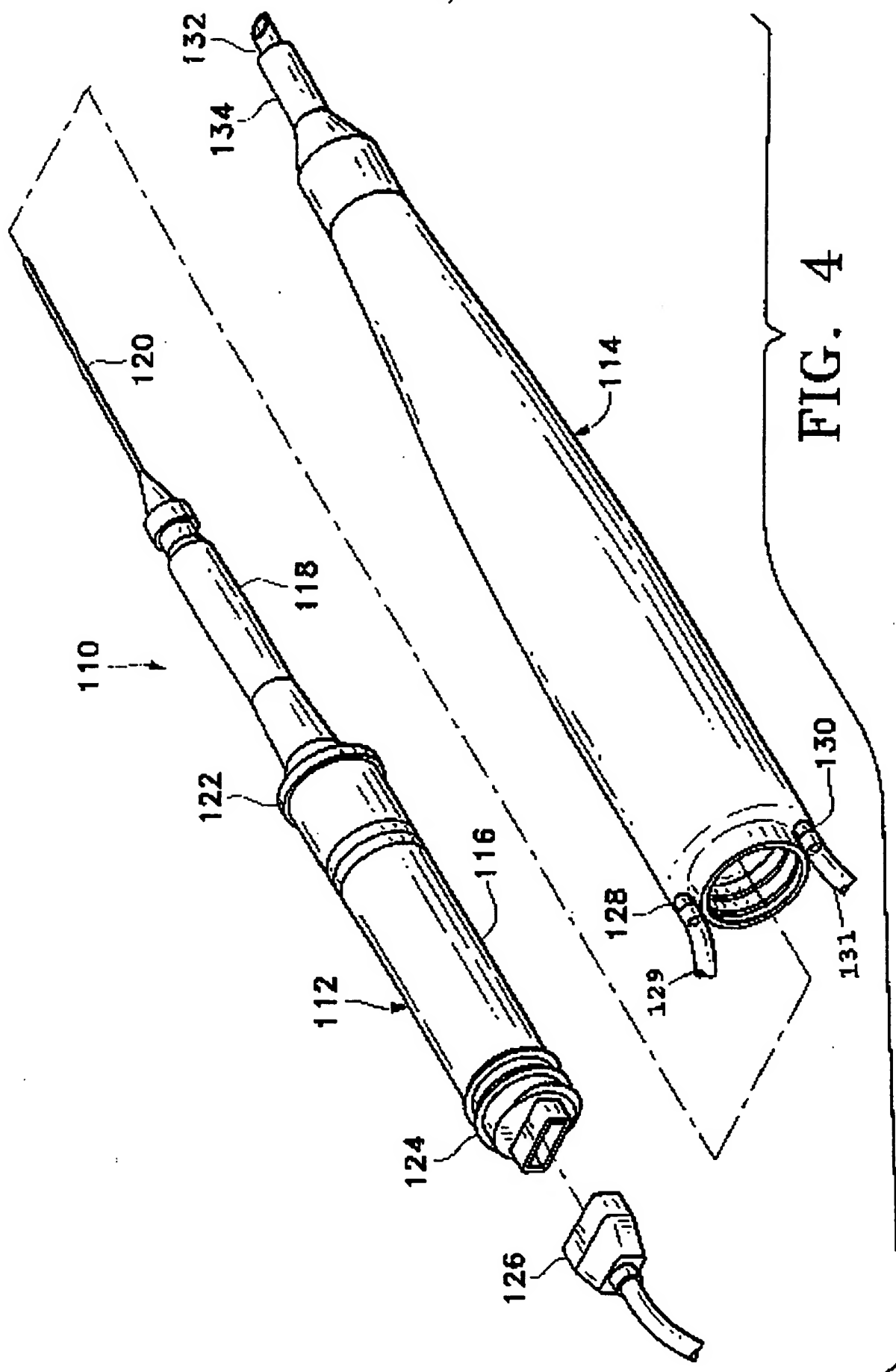
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